



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

AUG 29 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 75-00

Ms. Jeannie C. Wu
President
Ameripec, Inc.
6965 Aragon Circle
Buena Park, CA 90620

Dear Ms. Wu:

On April 3-17, 2000, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of Ameripec, Inc., located at the above address. At the conclusion of the inspection, you were presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (GMP). By reason of these deficiencies, the food products processed at your facility are adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found the following deficiencies related to beverage products filled and packaged at your facility:

1. Failure to take reasonable precautions to ensure that production procedures do not contribute contamination from any source. Specifically, glass shards and pieces in and on equipment found on numerous occasions during the inspection, and your firm is not cleaning these areas in a timely manner after breakage occurs, nor are you assuring that nearby uncapped bottles have not been contaminated with glass pieces.

We understand that your firm will experience glass breakage as part of normal manufacturing operations due in part to container defects and the actual movement of these glass containers on a moving assembly line. Even so, you must take reasonable precautions and preventative measures to ensure that open containers are protected from shattering glass pieces.

We note that you have developed standard operating procedures to control potential glass fragments from entering open containers of in-process beverage products. However, our investigator noted that in several instances, you did not follow the procedures found in the

written document entitled [REDACTED] For example, item number 8 of this document states that [REDACTED]

[REDACTED] However, glass shards and fragments were observed on the filling carousel, on the interior of the transfer wheel, and traveling with uncapped bottles on the conveyor line for bottling line [REDACTED] This line was not stopped and broken glass cleaned until pointed out by the FDA investigator.

2. Failure to take proper precautions to reduce the potential for contamination of food, food-contact surfaces, and food-packaging materials. These precautions could include adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means. Specifically, glass fragments were found on and around the [REDACTED] production line. This line does not use glass containers, therefore, this glass is presumably from the adjacent glass beverage filling line [REDACTED] Moreover, two filling carousel dispensers for the [REDACTED] production line were observed opened while the adjacent glass bottling [REDACTED] was running. These filling carousel dispensers when opened while the adjacent bottling line is operating, have no protection from glass fragments entering the dispensers.
3. Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces and food-packaging materials. Specifically, your current cleaning procedure which includes a high pressure washing of the broom used to sweep glass fragments from the processing floor could allow glass fragments to be projected onto the processing lines.

In addition, a broom used to sweep the processing area floor was observed being used on the conveyor line used to convey [REDACTED] containers during their filling operation. This broom comes in direct contact with the processing room floor.

4. Failure to clean and sanitize non-food-contact surfaces of equipment in the operations of food plants as frequently as necessary to protect against contamination. Specifically, a dark colored, grime-like substance was observed on the overhead structure of the upper covering for the bottle filling equipment on bottling line [REDACTED] This location was observed to be directly over open, exposed bottles of beverages in-process. In addition, the bar guides that are on each side where each new cap is stationed was also found to have an accumulation of a dark colored grime-like substance.

A grime-like substance was also noted on the plastic divider inside your tub washing machine. This tub washer is used to wash the tubs that hold filled [REDACTED] containers. These tubs come in direct contact with this plastic divider during the washing process.

5. Failure to take necessary precautions to protect food, food contact surfaces and food packaging systems from possible contamination with microorganisms or foreign substances. Specifically, soiled toilet paper was observed in the men's restroom. This was apparently being discarded directly on the floor of this room by employees using these facilities.
6. Failure to handle and maintain containers used to convey, hold and store work-in-progress or food during manufacturing or storage in a manner that protects against contamination. Specifically, plastic tubs that hold filled [REDACTED] containers were observed to have accumulated dirt inside the tub where [REDACTED] were being stored immediately after filling.

In addition, these containers were observed to be nested, allowing the bottom of each tub to come in direct contact with the filled containers of [REDACTED] inside the tub below. The bottom surfaces of these tubs were observed scarred and dirty.

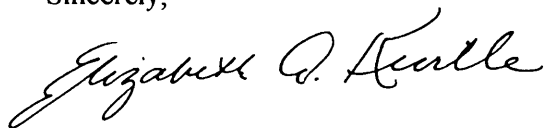
7. Failure to construct the plant in such a manner that drip or condensate does not contaminate food, food-contact surfaces and food-packaging materials. Specifically, condensate was observed accumulating and dripping directly over exposed bottles of in-process beverage containers in the filling process for filling line [REDACTED].
8. Failure to properly store equipment within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage area for pests. Specifically, the yard near the south outside wall of the processing facility was found to contain pallets and other material stored in a way that would not allow proper cleaning and pest control in this area.
9. Failure to provide adequate screening or other protection against pests. Specifically, screening was torn in the boiler room of the processing plant at ground level at the wall between the boiler room and the outside of the facility. This area measured approximately 5" by 7" in size. In addition, a door leading directly into the processing facility was observed opened to the outside and providing no barrier to entry of pests into the facility.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to the Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,

A handwritten signature in cursive script, reading "Elizabeth A. Keville".

Elizabeth A. Keville
Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief